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June 10, 2005

Commissioner Robert E. Nicolay  
Chairman, Certificate of Need Task Force  
Maryland Health Care Commission  
4160 Patterson Avenue  
Baltimore, Maryland 21215

Dear Commissioner Nicolay:

On behalf of the University of Maryland Medical System (UMMS), thank you for the opportunity to submit the following comments regarding the Maryland Health Care Commission's Certificate of Need Program to the CON Task Force. We have five recommendations described below:

1. CON Regulations for Licensure of Beds should be Amended to be Consistent with State Licensing Methodology
2. Performance Standards for Capital, Projects Involving Construction, Demolition or Renovation should be adjusted for larger Projects
3. Increase the Capital Expenditure Threshold Review from \$1.65 million to \$10 million
4. Deregulate Obstetrics Services from CON Review
5. Exempt Clinical Information Technology from CON Review

**1. CON Regulations for Licensure of Beds should be Amended to be Consistent with State Licensing Methodology**

*Maryland regulation should be amended to bring bed licensing and CON regulation of bed expansion into accord. The "140 percent rule", being institution-specific and based on a hospital's actual average daily census, is more reflective of a hospital's actual need than a jurisdictional bed need projection.*

The current Maryland acute care bed capacity licensing methodology allocates a maximum licensed bed capacity for each acute care hospital based on 140 percent of its annual average daily census. This equates to an average annual occupancy rate assumption of 71.5 %. The Maryland Health Plan through the Certificate of Need (CON) process requires that a hospital located within a specified jurisdiction have an average annual occupancy rate assumption for MSGA beds of 80%. Therefore, if a hospital requested a CON to build additional bed capacity legally licensable at 71.5% occupancy level, it would conflict with the regulatory standard established for evaluating bed increases. We believe that if this inconsistency in state licensing and regulation are not balanced, it could have a negative impact on hospital growth and patient access to acute care services in the State. While each approach is appropriate as applied to its own use, the two must be reconciled so that there is no potential conflict or

barrier for an acute care facility to submit a CON application for additional beds within a reasonable planning horizon timeframe.

**2. Performance Standards for Capital Projects Involving Construction, Demolition or Renovation should be adjusted for Larger Projects**

*UMMS recommends that MHCC establish different standards for obligating capital expenditures for larger projects (i.e. projects greater than \$60 million).*

This concern is focused on Section 10.24.01.12(3)(g)(i) and (ii), which applies performance standards for a health care facility to obligate 51 percent of its certified capital expenditure for the first phase of construction and up to 24 months to complete the first phase of the multi-phased plan and subsequently complete each additional phase within a 24 month period. For projects greater than \$60 million, this requirement would place an enormous burden on hospitals with large-scale projects that take 5-7 years to accomplish as we have seen with several of our facility renewal projects. For example, the development of the R Adams Cowley Shock Trauma Center, the Gudelsky Building (a critical care tower) and the current Weinberg facility project on the University of Maryland Medical Center campus established at the outset of the projects phase I plans that extended beyond 24 months and were on schedule. The 24-36 month timeframe to complete various phases of a large scale construction project is too short. The existing standards are too prohibitive and could obligate hospitals for financing expenditures prematurely in their project timelines.

**3. Increase the Capital Expenditure Threshold Review from \$1.65 million to \$10 million**

*UMMS is recommending that the capital threshold for CON review be increased from \$1.65 million to \$10 million to allow hospital providers to meet patient demand, implement patient safety programs in a more efficient manner and also to save the State's resources.*

Over the last several years, patient volumes and patient safety initiatives have significantly increased, requiring hospital providers to spend more capital dollars than in past years to meet this growing demand. These needs include the expansion of inpatient bed capacity, ambulatory clinic space, operating room capacity and patient safety initiatives such as information system technology and increasing the number of private patient rooms. Many of these projects are necessary to assure patient access and improve patient flow and safety and the capital requirements for these projects is usually more than \$1.65 million. To implement these projects, hospital providers must submit multiple applications to the Commission, delaying hospitals' abilities to implement necessary improvements in a timely manner to meet patient needs. In addition, inflation continues to drive the cost of construction materials, labor and technology, increasing the overall costs of capital improvement projects.

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Eighteen out of the 21 CON applications currently under review by the Commission exceed the \$1.65 million dollar expenditure threshold. Nine exceed the proposed \$10 million dollar threshold.

The State's Capital Expenditure Review Threshold is also below the mid-range among other states with CON review programs. Maryland's neighboring states' thresholds include Delaware (\$5 million), Virginia's (\$5 million) and the District of Columbia (\$2.5 million). The state of Massachusetts' capital threshold is \$10.2 million (the highest in the U.S.)

#### 4. Deregulate Obstetrics Services from CON Review

*Obstetrics Services (OB) should not be subject to the Certificate of Need regulations of the State Health Plan. OB is a basic health care service that should be provided by any community hospital that can offer a service that meets the quality standards established by recognized authorities, including the State Perinatal Guidelines.*

There is undeniable value in the regulatory process for many circumstances related to healthcare in Maryland. However, with regard to Obstetrics, the basic logic of the applicability of the current CON regulations is questionable. Hospitals can open free-standing birth centers without CON approval. They deliver babies in their emergency rooms and operating rooms in emergencies. They turn patients away who require this care, many of whom have not had adequate prenatal care. And finally, there are many subspecialty services that can be initiated without CON approval for the program as part of general medical/surgical services – oncology, neurosurgery, etc. Obstetrics is as basic a service as general emergency care. A community hospital established to meet community needs should, at a minimum, be able to provide for such a basic service. In reality, OB care is being provided at hospitals without a formal OB service, but in an environment that is less than optimal in terms of access, patient safety and quality care. Hospitals must be equipped and ready to deliver a baby at any time when transfer is not an option. This is very different from any other service. When a woman arrives in labor and the baby's head is visible, a hospital is not in a position to move that patient to another hospital. Hospitals should be able to provide the highest quality of care available in that circumstance. However, in the current environment, families in this situation must rely on hospitals without OB services and must rely on staff who rarely delivery babies or care for pregnant women and newborns to provide that service.

#### Health Policy Rationale:

- The State Health Plan and Certificate of Need regulations were created to “[develop] a health care system that provides financial and geographic access to quality health care at a reasonable cost for all citizens.” (COMAR 10.24.10.02)

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- While CON regulations are certainly appropriate in certain circumstances, OB is not one of them. The addition of OB capacity will not, in and of itself, drive an increase in the number of births. There is no danger of unnecessary utilization of OB services. No one has a baby because there is more capacity in the system to do so.
- Currently, a free standing birth center can be opened without CON approval.
- Despite not having a CON for OB services, any hospital will have to be able to provide OB-related services, including the ability to deliver and perform c-sections, stabilize infants, etc. Not having OB does not mean that women will not come to the closest hospital for care if they feel their needs are urgent. This is very different from other CON-regulated services.

Access:

- For individuals with limited access to care, the local hospital serves as a primary health care resource. Women who present at hospital emergency rooms in labor or with obstetrical-related problems generally do not have adequate prenatal care. Additional OB resources would add such access.
- The MHCC has established a standard for access to an OB program of less than a 30 minute drive. While a 30-minute drive time may seem reasonable to many individuals, it is completely unreasonable for individuals who rely on public transportation which is limited in many areas of the State. These are the same women who often fall into lower socioeconomic groups and are less likely to receive adequate prenatal care. These are the women who most frequently present at emergency rooms with pregnancy related complications (e.g., bleeding or preterm labor) or in active labor ready to deliver.
- The presence of women's health related subspecialties such as GYN oncology, general gynecology, and urogynecology are directly related to the presence of OB-GYN's. OB-GYN's do not typically practice at hospitals where there is no OB program. This limits the ability of that hospital to provide these services for their community.

Unnecessary Diversion of Critical Resources:

- Example: In Fiscal Year 2004 (July 1, 2003-June 30, 2004), 172 women in active labor were brought to North Arundel Hospital by ambulance. EMS providers know that the hospital does not have OB services; however, these patients were unstable enough to require transport to the closest hospital.
- Example: EMS diverts approximately 90 OB patients/year to other hospitals who would ordinarily come to North Arundel Hospital as their closest hospital.
- If there is no opportunity to transfer the woman to an OB facility, the delivery is done in the hospital Emergency Department or operating room.
- If the woman can be transferred, the hospital must stabilize the patient and then have her transferred by ambulance to another provider.

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- For women who walk into the hospital's emergency department in labor or with OB complications, the hospital must transfer her by ambulance (typically County EMS) to another provider.
- This utilization of critical EMS resources is unnecessary and a diversion from other community needs.

Quality and Patient Safety:

- A comprehensive community hospital should be able to provide the highest levels of quality and safety for any patient seeking care there. Deliveries and c-sections in emergency rooms and OR's which do not typically deliver this care and whose staff are not accustomed to providing this care do not meet this standard.
- While patients can often be transferred, sending a patient out when delivery is imminent is not an option.

There have been concerns expressed that eliminating OB from the CON review process would also eliminate the oversight that the MHCC has for ensuring the quality of the care provided by a new program. However, there are ample mechanisms for such assurance. The Maryland Perinatal System Standards must still be met by any provider of OB services – new or existing. These comprehensive standards (which were recently updated by a committee of perinatal care experts) cover every aspect of care including required staffing, ancillary services and equipment, policies and procedures for specific clinical processes, and physician support required for general obstetrics and perinatology, anesthesia, radiology, pathology, and pediatrics.

**5. Exempt Clinical Information Technology from CON Review**

*UMMS believes that Clinical Information Technology should be exempted from CON review.*

Clinical Information Technology (IT) capital investments including IT infrastructure, hardware and software applications should be viewed as comparable to major medical equipment which was deregulated under the Health Care Cost Containment Legislation in 1985. Since the primary benefits of new clinical information technology is not inconsistent with the State Health Plan, clinical information technology should be considered as business or office equipment that will improve patient safety in hospital and ambulatory settings, enhance the efficient and effective delivery of health care services, and is in the public interest.

There are a number of issues and initiatives driving changes in clinical healthcare IT including federal and state regulations. Taken together, these forces are creating what will become standards and requirements for how health providing hospitals and clinicians utilize Information Technology and online clinical knowledge. The expectations of what computers should and must do in the processes of healthcare are becoming clearer and more sophisticated than at any time in the history of healthcare.

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The use of modern and sophisticated clinical Information Technology in healthcare is no longer an option; it is a basic part of providing care to patients, managing complex healthcare organizations, supporting clinical research, and in educating and training physicians, nurses, pharmacists, and other healthcare professionals.

Thank you for the opportunity to provide comments on the Certificate of Need Program. We appreciate the opportunity to provide input into this process. If you should have any questions, I can be contacted at (410) 328-7410. Thank you.

Sincerely,

A handwritten signature in cursive script, appearing to read "Donna L. Jacobs", with a long horizontal flourish extending to the right.

Donna L. Jacobs  
Senior Vice President  
Government and Regulatory Affairs

CC: Edmond Notebaert, CEO, UMMS  
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